EXHIBIT 41

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804
This document relates to: Jennifer Artz v. Endo Health Solutions Inc., et al. Case No. 1:19-OP-45459	Case No. 17-md-2804 Judge Dan Aaron Polster
Darren and Elena Flanagan v. McKesson Corporation, et al. Case No. 1:18-OP-45405	
Michelle Frost, et al., v. Endo Health Solutions Inc., et al. Case No. 1:18-OP-46327	
Walter and Virginia Salmons, et al., v. McKesson Corporation, et al. Case No. 1:18-OP-45268	

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January 28, 2020

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* * *

balance a system that needs to maintain homeostasis, correct?

A. Exactly, yes.

Q. And then you go on to say:

The data on opioid exposure are somewhat muddied because many of those data were obtained from children of heroin abusers and had an overlay of several social and other factors that call those findings into question, period.

Do you see that?

A. Did I -- yes.

Q. Now, would you -- do you stand by that statement as you made it in 2016?

A. Yes, I did.

Q. And was that a recognition that, going from the science we are talking to the kind of patients on the clinical level, that many women who give birth to NAS children are not simply taking an opioid as prescribed, correct?

A. That is part of the contributing factor, yes.

Q. And if you're going to be looking at

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registries established for NAS, and then, lastly, a toxicology screen.

Q. So all of those things together allow you to diagnose a person who's currently 18 --

A. Yes.

Q. -- with NAS, obviously when they were born.

A. Yes.

Q. But NAS itself as a disease condition is a disease condition of birth?

A. Yes.

Q. Or about the perinatal period, right?

A. That is correct.

Q. Now, looking at what's been marked as Exhibit 11 and is in front of you, if you go to, I think, the middle of that paragraph?

A. Um-hmm.

Q. It says -- starts with the word "published."

Do you see that?

A. Yes.

Q. It says:

Published follow-up studies of NAS babies, however -- comma, however, comma, show minimal long-term effects related to prenatal opioid exposure.

Do you see that?

A. Yes, I do.

Q. And then you go on to talk in the next sentence about Baldacchino; is that correct?

A. Yes.

Q. So at least as of your August 2018 report, it was your understanding of the literature that published follow-up studies of NAS babies showed minimum long-term effects related to prenatal opioid exposure, correct?

A. That is correct.

Q. And then when you -- if you go to what has been marked as Exhibit 8, which is your December report.

A. Um-hmm.

Q. You say in the middle of that paragraph starting with the word "thus," in paragraph 7, my apologies. You see it says:

Thus, prenatal opioid exposures have

* * *

A. All I'm saying is that this case that we're preparing for is to address children who had opioid exposure and were diagnosed with NAS at birth. We're not really, in this situation, not focusing on children who had fetal alcohol syndrome.

Q. And this monitoring program doesn't do anything to address poverty, correct?

A. No, it doesn't.

Q. It doesn't address parental abuse of children, correct?

A. Absolutely.

Q. It doesn't address negligence by parents, correct?

A. Yes, correct. Although it makes it much more difficult, because when you look at the monitoring surveillance program, it requires, you know, quarterly or biweekly evaluations in the first year after birth, and it requires regular evaluation including home visits during this -- this child's sort of preschool years.

So if there is abuse, if there is negligence, then it will be picked up much

earlier before it has the ability to escalate and make this child's brain damage worse; the brain damage, meaning, what occurred from opioid exposure during the prenatal period.

Q. And what happens if the mother doesn't bring the child in for those evaluations?

A. Again, I think the protocol includes a paragraph, if you look at it, there are certain barriers for overcoming those. It's paragraph number 4 on the page just before my signature page and it says:

Barriers for implementing these monitoring protocols must be anticipated and addressed. These may include providing funding for transportation to scheduled assessments or making the transport arrangements, providing token compensation to participants facilitating access by offering home visits or assessments at a location convenient for the parent/caregiver, consideration for living situation and other barriers.

So I think it is important that we anticipate those barriers and see why there is

no compliance, that the mother is -- why the mother is not bringing this child in for evaluations, and trying to overcome those.

Q. Now, one of the ways you suggest we may overcome that is by offering some financial incentives to the parents for bringing their kids in?

A. Yes.

MR. EHSAN: I'm going to mark --

(Exhibit 14 marked for identification.)

BY MR. EHSAN:

Q. Doctor, you've been handed what's been marked as Exhibit 14. This is an article titled Measuring Socioeconomic Adversity in Early Life; is that correct?

A. That is correct.

Q. And are you the first author on that article?

A. Yes, I am.

Q. And this was published in?

A. 2019.

Q. 2019.

So after your first declaration,

before your second declaration, correct?

A. That is correct.

Q. Are you familiar with the content of the article?

A. Yes, I am.

Q. What was the aim of your study?

A. The aim of this study was to develop a way of assessing socioeconomic adversity.

For decades, socioeconomic status had been assigned after looking at simply economic factors without taking account of the social factors that the -- the child or -- and the mother and the child may be experiencing.

And so this was one attempt at creating an index that will account for social as well as economic factors to assign socioeconomics or to estimate the socioeconomic adversity.

Q. So to the extent that socioeconomic status was perhaps not a refined concept, it could have made studies who were trying to control for socioeconomic status potentially less reliable because they were not taking a fine-grain approach to it, as you suggest in

your article, correct?

A. That is correct.

Q. In the -- on the bottom of the first page, there's a colored box that has a title: Key notes.

Do you see that?

A. Yes, I do.

Q. And could you read the second note, the second bullet?

A. Sure.

Social and familial factors significantly contribute to early life adversity which leads to worse long-term physical/mental health outcomes.

Q. And you agree with that statement?

A. Yes.

Q. And the next bullet states:

Factors predicting socioeconomic adversity in early life include: Marital status, household structure, annual income, education, and health insurance.

Did I read that correctly?

A. That is correct.

Q. So all of these factors would be

relevant to how the child does in terms of their physical and overall health outcomes, correct?

A. That's correct.

Q. And if you go to -- my vision here -- if you go to page 2 of the article.

A. Okay.

Q. You state, the left paragraph, that first indented -- left column, first indented paragraph starting "instead."

Do you see that?

A. Starting where?

Q. So the second page of the article --

A. Yeah.

Q. -- left-hand column, the first indented the paragraph --

A. Yeah, okay.

Q. -- that starts with "instead."

A. "Instead of focusing."

Q. And it states:

Instead of focusing -- or you state:

Instead of focusing on poverty, we call for considering socioeconomic adversity more broadly as that resulting from social,

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from conferences or colleagues that you think is reliable, correct?

A. Yes.

Q. And in terms of the individualized aspect, I assume that you treat each of your kids or your patients as individuals.

A. Um-hmm.

Q. Yes?

A. That's true.

Q. And so what that means is that when you make clinical decisions about their care, you weight risks and benefits and exercise your clinical judgment in a way that is specific to each child; is that fair?

A. That is correct.

Q. Okay. And so when we think about this population of NAS children that we have been talking about, would you agree with me that each NAS child is unique in his or her genetic makeup?

A. Yes, absolutely.

Q. They have their own unique genome --

A. Yes.

Q. -- that is made up of the unique and

individual genetic makeup of each parent, right?

A. That is right.

Q. Okay. And each parent that is contributing to this child's genetic makeup have their own unique and individual epigenetic influences through their life, right?

A. That is correct.

Q. And are you one that believes that that could be transgenerational effects that we see down the road from epigenetic influences?

A. Yes, there is fairly good evidence. It's still pretty shaky, but there's fairly good evidence accumulating for that.

Q. And so to the extent the parents, and particularly the mother who we are looking at who has used opioids at some point during her pregnancy for different reasons, each of their genetic makeup and their epigenetic influences get passed on to their NAS child, right?

A. That is correct.

Q. Okay. And would you agree with me that each NAS child has very individual and

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with their diagnosis. Their -- I see no reason to question their diagnosis.

Q. Understood. And so we know, then, for this population of NAS children that each child is going to be different in terms of what NAS scale was used, which kind of health care provider filled it out, whether it was a nurse, doctor, PA, and there will be differences in how they're treated based on how they're scored, right?

A. That is correct.

Q. And each child, each NAS child would also therefore differ in terms of their immediate neonatal and post birth care?

A. There will be differences, absolutely, however, there's at least two studies that have shown that when charts were reviewed, where the diagnosis had been documented in the chart, they went back and reassessed those kids, and they showed that those diagnoses were -- were accurate. So there is some reproducibility and -- and there are quality improvement initiatives going on in, you know, different hospitals at different

times, which have tended to reduce the inter-rator sort of variations so that there is -- there's, you know, a uniform way of assessing the child.

Q. And is there -- am I correct that each NAS child will differ in terms of the severity of the NAS and particularly depending upon whether or not the mother was exposed to other substances?

A. That is true.

Q. Right?

A. Yeah.

Q. And each NAS child is going to be different in terms of their performance or how do I say it, health assessment at one year of age, right?

A. Absolutely.

Q. I take it you're familiar with the data and studies on how important that first year of life is to the overall lifetime performance or development of the child?

A. Yes, there -- there is a lot of data to support the developmental origins of, you know, subsequent disease patterns and things

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substance abuse, et cetera, they're still talking about children born from mothers exposed to opioids. So that still shows that it's the opioid exposure that is a primary factor. This is, you know, in 1998.

Q. Agreed.

So let me ask you, then, about -- you had mentioned the Patrick study --

A. Yes.

Q. -- earlier in your testimony too, so I know you've seen it.

Do you agree that the predictability of the impact of NAS on a child will vary depending upon drug type, cumulative opioid exposure, and other substances like cigarette smoke?

A. Yes, I agree.

Q. Okay.

A. But the opioid exposure is contributory and a major player.

Q. And -- but you're acknowledging there are a lot of other potential contributors?

A. Sure.

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and D may not be there. Information may be missing on that, but if there is a toxicology screen that is positive, I would include that child within the class so that we can start the monitoring and the surveillance and at least rule out the -- the long-term effects of the opioid exposure.

Q. Well, there are NAS children who have been diagnosed with NAS based on symptoms, where the blood and cord blood and meconium tests are not positive, right?

A. That is right.

Q. And there are NAS children -- or strike that.

There are children exposed to opioids in utero, who have positive cord blood or positive meconium and yet don't fulfill the NAS criteria and, therefore, are not diagnosed with NAS, right?

A. True, NAS --

Q. So you're going to include in your class babies who have not been diagnosed with NAS, if they have positive cord blood or positive meconium?

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